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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,169	03/24/2005	Young-Min Lee	26689U	2581

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,169	LEE ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-29* is/are pending in the application.

4a) Of the above claim(s) *22-25* is/are withdrawn from consideration.

5)☒ Claim(s) [illegible] is/are allowed.

6)☒ Claim(s) *7-11,13,14,18-21 and 26-29* is/are rejected.

7)☒ Claim(s) *12,15-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *May 3, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of **Group I**, claims 7-17 and 26-29 and **SEQ ID NO: 45** in the reply filed on June 19, 2007 is acknowledged. The traversal is on the ground(s) that the claim set share a special technical feature and claims possess unity of invention therefore, restriction is improper. This is not found entirely persuasive because claims 22-23 are drawn to a synthetic JEV comprising a mutation. Claims 24-25 are drawn to a method for the expression of heterologous genes. Upon review and consideration **Groups II and III will be rejoined.** Groups IV-V are not rejoined because they are drawn to a different invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 19, 2007.

Status of the Claims

Claims 7-29 are pending. Claims 1-6 have been canceled. Claims 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 19, 2007.

Claims 7-21 and 26-29 are under examination.

Claim Objections

Claim 28 (New) is objected to because of the following informalities: Claim 28 is a duplicate claim number because there are two Claims numbered 28. Claim 28 (Original) is followed by another Claim 28 (New), which will be considered claim 29 for examination purposes. Appropriate correction is required.

Claim 10 is objected to because of the following informalities: The claim is not grammatically correct in line two of the claim. The claim reads, "sequence is not exist", which is not clear. Appropriate correction is required.3

Claims 12 and 15 are objected to because of the following informalities: The claims contain multiple sequence identifiers, which are drawn to nonelected inventions. Appropriate correction is required.

Claim 27 is objected to because of the following informalities: The claim contains subject matter that is drawn to a nonelected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. It is apparent specific DNA sequences are required to practice the claimed invention. As such they must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. If it is not

so obtainable or available, an enabling deposit of the DNA may satisfy the requirements of 35 U.S.C. 112, first paragraph. It is noted that the Applicants have deposited the DNA but there is no indication in the specification as to public availability. Therefore, a deposit at a recognized depository may be made for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years. Or 5 years after the last request for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and

(e) the deposit will be replaced if it should ever become nonviable.

It is not clear from the disclosure that deposits of KCTC 10346BP and KCTC 10347BP meet all the criteria set forth in MPEP 608/01 (p)(C), items 1-3. Assurance of compliance may

be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined below:

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

8. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both,

under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, and the complete taxonomic description. The specification includes reference to the deposit of the vectors, however the **address of the depository** was not found. As a possible means of completing the record, applicants may submit a copy of the deposit receipt.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain the phrase "elements originated from" which does not distinctly define the claimed invention. The term "elements" is indefinite and is not defined in the specification. The claim language can be interpreted as a small portion of the JEV cDNA clone.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10, 13, 18 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by **Mishin** et al. (Virus Research, Dec. 2001, Vol. 81, No. 1-2, pages 113-123).

The claimed invention is drawn to a full length infectious and genetically stable cDNA clone of Japanese encephalitis virus (JEV), wherein the cDNA clone contains a promoter at the beginning of 5' end of a DNA sequence corresponding to a JEV genomic RNA and a restriction endonuclease recognition sequence at the 3' end of the DNA sequence as a runoff site, wherein the promoter is SP6 or T7, wherein the restriction endonuclease recognition sequence does not exist in the JEV genomic RNA, wherein the JEV genomic RNA consists of a 5' nontranslated region (NTR), a single polypeptide region, and a 3' NTR, an infectious JEV RNA transcript synthesized from the cDNA clone, and a vector including the JEV cDNA clone.

Mishin et al. (hereinafter Mishin) teaches an infectious clone of Japanese encephalitis flavivirus wherein the promoter is at the 5' end and the endonuclease restriction sites are at the 3' end (Abstract, page 114, 2nd column and page 116, Fig. 2). The promoter is T7 and a plasmid contains the full size JEV cDNA (Abstract). Mishin teaches the flavivirus RNA has a short 5' untranslated region and synthetic RNA (page 118, 1st column 2nd paragraph).

Claims 7-11, 13, 18-19, 21 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by **Zhang** et al. (Journal of Virological Methods, Aug. 2001, Vol. 96, No. 2, pages 171-182).

The claimed invention is drawn to a full length infectious cDNA clone of Japanese encephalitis virus (JEV) described above, wherein the restriction endonuclease recognition sequence is Xho I or Xba I. The claimed invention is also drawn to an infectious JEV RNA transcript synthesized from the cDNA clone, wherein the virus-unrelated nucleotides are removed by treating mung bean nuclease (MBN), and a cell transfected with the JEV RNA transcript.

Zhang et al. (hereinafter Zhang) teaches a technique to produce genome length cDNA stable clone from Japanese encephalitis virus, which is infectious (Abstract). The cDNA has a T7 promoter at the 5' end and a "run-off" transcript with vector sequences at either end (Abstract). The full-length amplicon was cloned into a vector under the SP6 promoter (Abstract). Zhang teaches the restriction endonuclease recognition sequence is Xho I (Abstract). The RNA transcript was synthesized from the clone (page 174-175, connecting paragraph). Zhang teaches Japanese encephalitis virus genome lacks a poly-A tail at the 3'-terminus (page 176, 1st column). Zhang teaches RNA transcripts were transfected into BHK-21 cells (page 175, 1st column, 1st paragraph). Zhang teaches Japanese encephalitis virus has short untranslated regions (page 172, 1st column, 1st paragraph).

Claims 7-11, 13, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by **Sumiyoshi** et al. (Journal of Virology, Sept. 1992, Vol. 66, No. 9, pages 5425-5431).

The claimed invention is drawn to a full length infectious cDNA clone of Japanese encephalitis virus (JEV) described above, wherein the virus-unrelated nucleotides are removed by treating with mung bean nuclease.

Sumiyoshi et al. (hereinafter Sumiyoshi) teaches a full length infectious cDNA copy of the JEV genome was constructed (Abstract). Sumiyoshi teaches the promoter is T7 and RNA runoff products have the same 5' and 3' ends as the authentic JEV genome RNA (page 5427, 2nd column, middle paragraph). The clone was cut with Xba I and treated with mung bean nuclease to remove extra bases (page 5426, 2nd column, 2nd paragraph and page 5427, 1st column, 2nd paragraph). Sumiyoshi teaches in vitro RNA synthesis of JEV RNA (page 5427, 1st column, 2nd paragraph). BHK-21 cells were used for RNA transfection (page 5426, 2nd column, 4th paragraph).

Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by **Chang** et al (Journal of Virology, May 2000, Vol. 74, No. 9, pages 4244-4252).

The claimed invention is drawn to an anti-JEV vaccine containing elements originated from the JEV cDNA clone.

Chang et al. (hereinafter Chang) teaches plasmid vectors containing Japanese encephalitis virus (JEV) DNA were used to successfully vaccinate animals (Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim7-11, 13, 18-21 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Zhang** et al. and **Sumiyoshi** et al. as applied to claims 7-11, 13, 18-21 and 29 above, and further in view of **Chang** et al. (Journal of Virology, May 2000, Vol. 74, No. 9, pages 4244-4252).

The claimed invention is drawn to a full length infectious cDNA clone of Japanese encephalitis virus (JEV) described above and: a diagnostic reagent containing elements originated from the cDNA clone; an anti-JEV vaccine containing elements originated from the JEV cDNA clone; and a therapeutic agent comprising the JEV cDNA as active ingredients.

The teachings of Zhang and Sumiyoshi are described above. Neither Zhang nor Sumiyoshi teach using the cDNA clone as a diagnostic reagent, a vaccine or a therapeutic agent.

Chang et al. (hereinafter Chang) teaches plasmid vectors containing Japanese encephalitis virus (JEV) DNA were used to successfully vaccinate animals (Abstract).

Zhang and Sumiyoshi teach about full length infectious cDNA clones of Japanese encephalitis virus and infectious DNA constructs. Chang teaches JEV DNA vaccine is effective. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the full-length cDNA infectious clones as diagnostic tools and for therapeutic/vaccine use. The person of ordinary skill in the art would have been motivated to use the full-length cDNA infectious clones because Zhang and Sumiyoshi teach about the effectiveness *in vitro* and *in vivo*, and reasonably would have expected success because of the teachings of Zhang, Sumiyoshi and Chang.

Claims 7-11, 13-14, 18-21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Zhang** et al. and **Sumiyoshi** et al. as applied to claims 7-11, 13, 18-21 and 29 above, and further in view of **Schumacher** et al. (Journal of Virology, Dec. 2000, Vol. 74, No. 23, pages 11088-11098).

The teachings of Zhang and Sumiyoshi are described above. Neither Zhang nor Sumiyoshi teach bacterial artificial chromosome (BAC) is used for a vector.

Schumacher et al. (hereinafter Schumacher) teaches about the complete genome of Marek's disease virus, which was cloned in *Eschericia coli* as a bacterial artificial chromosome (BAC) vector, wherein an infectious clone was obtained.

Zhang and Sumiyoshi teach about full length infectious cDNA clones of Japanese encephalitis virus and infectious DNA constructs. Schumacher teaches about the use of BAC vector to obtain an infectious clone. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a BAC vector as taught by Schumacher in the JEV clone as taught by Zhang and Sumiyoshi. The person of ordinary skill in the art would have been motivated to use a BAC vector because Schumacher teaches the clone recovered from BACs was indistinguishable from the one of the parental virus (Abstract), and reasonably would have expected success because of the teachings of Zhang, Sumiyoshi and Schumacher.

Allowable Subject Matter

Claims 12 and 15-17 are free of the prior art.

Claims 12 and 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

September 4, 2007

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